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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,391	03/10/2004	Eleanor Schuler	920607-95597	4322
23644	7590	05/06/2005	EXAMINER	
BARNES & THORNBURG			ALTER, ALYSSA M	
P.O. BOX 2786			ART UNIT	
CHICAGO, IL 60690-2786			PAPER NUMBER	

3762

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/797,391

Applicant(s)

SCHULER ET AL.

Examiner

Alyssa M Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 08/16/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 5 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing "implanted within the body" in claims 6 and 12 to -- adapted to be implanted within the body--.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no apparatus mentioned in claim 5. The examiner recommends substituting "according to claim 5" with --according to claim 6--.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-10 of U.S. Patent No. 6,681,136. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims meet the limitations of the applications claims except for the delivery of waveforms to a blood pressure regulatory point. Since modulating blood pressure effects cardiac control, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modulate blood pressure in order to affect cardiac control.
2. Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/781,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims meet the limitations of the applications claims except for the delivery of waveforms to a blood pressure regulatory point. Since modulating blood pressure effects cardiac control, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modulate blood pressure in order to affect cardiac control.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3-6 and 10-12 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kieval et al. (US 6,522,926). Kieval et al. discloses a device to "be used to increase or decrease blood pressure, sympathetic nervous system activity and neurohormonal activity, as needed to minimize deleterious effects on the heart, vasculature and other organs and tissues"(col. 21, lines 11-14) by activating the baroreceptors. Kieval et al. also discloses in column 21, lines 15-16 that "the baroreceptor activation devices described previously may also be used to provide antiarrhythmic effects". As seen in figure 3, "the control system 60 generates a control signal as a function of the received sensor signal. The control signal activates, deactivates or otherwise modulates the baroreceptor activation device 70. Typically, activation of the device 70 results in activation of the baroreceptors 30"(col. 9, lines 33-37). The examiner considers the control system to be the storage area where the signals are generated.

In the alternative, Kieval et al. discloses the claimed invention except for the memory to store waveforms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control system and method as taught by Kieval et al. with a memory to store waveforms since it was known in the art that storing and recording data can provide physicians with information on the status of their patient.

As to claims 3, “the transdermal connections may be replaced by cooperating transmitters/receivers to remotely communicate between components of the control system 60 and/or the sensor 80 and baroreceptor activation device 70”(col. 10, lines 6-10).

As to claim 4, figures 10A and 10B display “the magnetic field created by the electromagnetic coil 224 may be alternated such that the magnetic particles 222 vibrate within the vascular wall 40. When the magnetic particles are repelled, attracted, rotated, vibrated or otherwise moved by the magnetic field created by the electromagnetic coil 224, the baroreceptors 30 are mechanically activated”(col. 14, lines 29-35)

As to claims 5 and 12, “the baroreceptor activation device 70 may comprise a wide variety of devices which utilize mechanical, electrical, thermal, chemical, biological, or other means to activate baroreceptors 30”(col. 7, lines 41-44). “All of the specific embodiments of the baroreceptor activation device 70 are suitable for implantation”(col. 8, lines 11-12).

As to claim 10, "the electromagnetic radiation transmitter 66 and antenna 324 may be used to deliver electromagnetic radiation (e.g., RF, microwave) directly to the baroreceptors 30 or the tissue adjacent thereto to cause localized heating, thereby thermally inducing a baroreceptor 30 signal"(col. 18, lines 65-67 and col. 19, line 1).

As claim 11, "refer now to FIGS. 13A and 13B which show schematic illustrations of a baroreceptor activation device 280 in the form of an intravascular electrically conductive structure or electrode 282"(col. 16, lines 1-4).

2. Claims 2, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval et al. (US 6,522,926). Kieval et al. discloses the claimed invention except for the digital format and digital to analog converter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the blood pressure control system and method as taught by Kieval et al. with digital format and analog to digital converter since it was known in the art that using and storing of digital signals instead of analog signals accounts for less information being lost due to interference, since it was known in the art to use a analog to digital converter for changing data into digital signals to provide a conventional system that quickly converts the data into digital format for easy processing.

3. Claims 2 and 9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kieval et al. (US 6,522,926). Kieval et al. discloses a control system 60, with a memory 62 and a processor 63, which meet the definition of a computer.

In the alternative, Kieval et al. discloses the claimed invention except for the computer with separate storage areas. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the blood pressure system and method as taught by Kieval et al. with a computer with separate storage areas, since it was known in the art that computers compatible systems provided efficient programming and storing capabilities which automatically function to store multiple data files to allow more data to be used and selected.

### ***Claim Objections***

1. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 has the same limitations as the ones set forth in claim 5. Therefore, claim 12 fails to further limit claim 5. The examiner recommends changing claim 12 to read on claim 6 instead of claim 5.

### ***Conclusion***

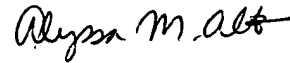
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Terry et al. (US 5,707,400) discloses treatment of hypertension.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Alyssa M Alter  
Examiner  
Art Unit 3762

  
JEFFREY R. JASTRZAB  
PRIMARY EXAMINER

5/102/JS